EXHIBIT 21

From:	Daniel Sessler
To:	Hansen, Gary; russell olmsted
Sent:	11/16/2010 5:52:42 PM
Subject:	Re: Emailing: PE Statistics.xlsx

Hi Gary,

On the Statistics/P-value spreadsheet, the mean value for the 422 cover (warm) in Utrecht is wrong -- fortunately! The increase with the 635 cover on ambient or warm in Amersfoort seems substantial, roughly a factor-of-five-to-ten. The only reason it isn't statistically significant is that there were only five measurements. Why are the results with that cover so different in the two hospitals? Aside from that one test, the results look good...

What clinicians will want to see is basically particle counts under the three test circumstances (Off, Amb, Warm). Any substantial increase will concern them and basically validate Scott's point that forced-air warming increases risk. We can try to convince them that the increase isn't important or that the operating rooms still meet DIN standards, but that will be a bit tricky.

Possibly the best statistical approach would be an ANOVA with cover type, hospital, and warmer setting (off, amb, warm) as factors. But perhaps it would be best to consider the hospitals together since that isn't really a factor of interest; and cover type could be unpaired. That would leave cover type as an unpaired factor and warmer setting as the repeated-measures factor.

Regards, Dan.

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On 11/15/10 3:13 PM, "Gary Hansen" <ghansen@arizant.com> wrote:

> <<PE Statistics.xlsx>>
> Hello Dan and Russ,
>
> In the attached file, you will find the raw data used for the two
> reports. Recall that there were two sites (Amersfoort and Utrecht). At
> each site, two different blankets were tested (522 upper body and 635
> underbody). For each blanket, three conditions were tested (no air,
> ambient air, and warm air). For each condition, particles were sampled
> for five one-minute intervals.
>
> The fourth condition (table 1 in the report) is interesting only for the
> insight it adds to the basic filtration capacity of the room. This is
> the way that ORs are normally tested per the DIN 1946 standard, but,
> it's not relevant to our research question. In this case, no patient,
> drapery, or Bair Hugger were present - only the bare OR table. The only
> reason I would mention it is that the Hybeta people were surprised to
> see that counts were significantly better with a realistic patient
> setup. They wanted to say that actual particle exposure for patients is
> probably better than their conventional numbers would indicate.
>
> Russ, you asked about the reference particulate load. It is adjusted to
> be 1.0E6 particles per cubic foot.
>
> Bear in mind that DIN 1946 is intended to verify the effectiveness of
> operating room filtration. Therefore, it's cut-and-dried in its
> requirements; either an OR meets the standard or it does not. The
> authors did not envision making comparisons, so a statistical treatment
> is missing from the document. For the purposes of pass/fail, PE is
> calculated using the single worst one-minute sample of the collection.

> But, that doesn't mean we need to do the same for a scientific study.
>
> Concerning statistical treatment of PE data, I can think of two possible
> approaches. The first is perform a T-test comparison on the various
> permutations of the test conditions, similar the Rutala paper. I've
> attempted this in the attached spreadsheet. Note that none of the
> differences are significant to within 95% confidence. It won't escape
> notice that the number of samples is small.
>
> The other approach is to use the sampling error of the particle counter,
> then compare worst-case samples as suggested by the standard. We can
> probably obtain the estimated sampling error of the device from Hybeta.
> However, I think this approach is less defendable because the variance
> is probably not due to machine error, but rather to the random variation
> in particle concentrations within the room at various times.
>
> Concerning the level of detail in the methods section, that should be no
> problem. It's covered extensively in the attached report. I can also
> assist with questions, having a fair comprehension of how the work was
> done.
>
> Gary
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